



**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

**In re: PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE
LITIGATION**

THIS DOCUMENT RELATES TO:

State of Montana v. Abbott Labs., Inc., et al.,
CA No. 02-CV-12084-PBS

MDL NO. 1456
Civil Action No. 01-12257-PBS
Judge Patti B. Saris

Chief Magistrate Judge Marianne B.
Bowler

**DEFENDANT BAYER CORPORATION'S CORRECTED FIRST MOTION TO
COMPEL PLAINTIFF THE STATE OF MONTANA TO PRODUCE A RULE 30(B)(6)
WITNESS¹**

Defendant Bayer Corporation ("Bayer") hereby moves to compel Plaintiff State of Montana to produce witnesses in response to Bayer's Notice of Rule 30(b)(6) Deposition. This Notice, which was served on January 31, 2006 (attached hereto as Exhibit A), requests a witness or witnesses to testify concerning Bayer's 2001 AWP Settlement Agreement with Montana and Montana's use of the Average Sales Price data provided by Bayer for all its products pursuant to those Settlement Agreements. Montana has declined to produce a single witness to testify in response to this Rule 30(b)(6) Notice.² In further support of this Motion to Compel, Bayer states as follows:

¹ Bayer Corp.'s First Motion to Compel Plaintiff the State of Montana to Produce a Rule 30(b)(6) Witness filed on April 4, 2006, mistakenly attached the incorrect Notice of 30(b)(6) Deposition as Exhibit A. This filing corrects that error by attaching as Exhibit A the appropriate Notice of 30(b)(6) Deposition submitted by Bayer Corp. on January 31, 2006, as described in Paragraph 3 of this Motion. In all other material respects this Motion is the same as the Motion filed on April 4, 2006.

² The State of Nevada in a related AWP action now pending in State court in Nevada, *State of Nevada v. Abbott Laboratories, et al.*, Case No. CV02-00260 (Nevada I), received an identical

1. In 2001, Bayer entered into a State Settlement Agreement with Montana, which was executed on Montana's behalf in February 2001 (the "2001 Settlement Agreement"). This 2001 Settlement Agreement resolved Montana's allegations that Bayer had inflated the AWP of certain products – the same allegations raised in the instant action.³

2. Under the terms of the 2001 Settlement Agreement, Bayer was required to begin submitting to Montana the Average Sales Price (as defined in the Agreement) for *all* its products, not simply those medicines specifically named in the Agreement. Bayer began producing this required ASP information for all its medicines on a quarterly basis in 2001. At this time, Bayer was the only pharmaceutical company providing ASP data for its products. State officials with the National Association of Medicaid Fraud Control Units ("NAMFCU") touted Bayer's agreement to provide the data as providing "unprecedented access to true market prices," which "will provide you an extraordinary opportunity to compare providers' real acquisition costs with Medicaid reimbursement prices and, we believe, provide you the basis for determining where and how Medicaid prices should be adjusted." *See* Letter from NAMFCU Drug Pricing Team to Medicaid Pharmacy Directors (January 29, 2001), p. 2, attached hereto as Exhibit B.

3. On January 31, 2006, Bayer served a Rule 30(b)(6) Notice on Montana. This Notice directs that Montana produce a witness or witnesses on the following two subjects, which are specific to Bayer:

- Montana's use or consideration of Bayer ASP Information, including how or if such Bayer ASP Information has been used, relied upon, referenced, or considered in

Bayer Rule 30(b)(6) Notice and has similarly declined to produce a witness or witnesses in response to the Notice. *See infra* ¶ 6.

³ The 2001 Settlement specifically covered the following six Bayer products: Koate®-HP, Kogenate®, Konyne-80®, Gamimune® N 5% and 10%, and Thrombate® III. These were the only Bayer products identified as at issue in the course of the investigation.

evaluating, revising, or setting payments to Providers under Montana's Medicaid Program.

- Communications between Montana and NAMFCU concerning the Bayer 2001 Settlement (or any investigation or inquiry that preceded this Bayer 2001 Settlement), including internal analysis, memoranda, reports, and reviews related to communications with NAMFCU.

Exhibit A, at 2-3.

4. Testimony on these topics by a Montana representative is relevant and important to Bayer's challenges to Montana's claims. It appears that Montana has made absolutely no use of the Bayer ASP information, despite the NAMFCU correspondence and despite having regularly received this information on a quarterly basis since 2001. Among other things, Montana's failure to make any use of the Bayer ASP information since 2001 shows that the State cannot establish any damages arising from Bayer's alleged failure to provide similar information to the State for the period before 2001.

5. Plaintiff Montana has declined to identify or produce a single witness to testify regarding Bayer's Rule 30(b)(6) Notice, contending in part that no person can be identified with sufficient knowledge to testify on the identified subjects on the behalf of the State.

6. Rule 30(b)(6) requires Montana to designate a person with knowledge of the identified topics on matters within the State's knowledge. *See McLellan Highway Corp. v. United States*, 95 F.Supp. 2d 1, 10 (D. Mass. 2002). In addition, the State has an obligation to prepare the identified deponent to testify on matters not personally known to the deponent, but known by the State. *See Alexander v. FBI*, 186 F.R.D. 137, 141 (D.D.C. 1998). The State also has an obligation to "make a reasonable attempt to ascertain information reasonably available to

[it]" in preparing a witness to testify. *Big Top USA, Inc. v. The Wittnern Group*, 183 F.R.D. 331, 339 (D. Mass. 1998) (Saris, J.). Montana has not complied with these obligations here.

7. Bayer served a similar Rule 30(b)(6) request on the State of Nevada in a related AWP action now pending in State court in Nevada, *State of Nevada v. Abbott Laboratories, et al.*, Case No. CV02-00260 (Nevada I) (attached hereto as Exhibit C).⁴ Counsel for Nevada in this Nevada state court action also represents Montana in the instant action. Like Montana, the State of Nevada has also declined to produce a witness for questioning by Bayer on the topics raised by the Rule 30(b)(6) Notice.⁵

WHEREFORE, Bayer requests that the Court grant its motion, and compel the State of Montana to produce a Rule 30(b)(6) witness on the topics identified in Bayer's Notice within 14 days of the Court's Order.

Certification Pursuant to Local Rules 7.1 and 37.1

Pursuant to Local Rules 7.1(a)(2) and 37.1 of this Court, the undersigned counsel certifies that counsel for Bayer has conferred unsuccessfully with Montana's counsel in an effort to reach a resolution on the Rule 30(b)(6) discovery request on which, as identified above, the parties have reached impasse.

⁴ Rule 30(b)(6) of the Nevada Rules of Civil Procedure is identical to its counterpart in the Federal Rules of Civil Procedure.

⁵ Unlike Montana, Nevada initially designated a witness to testify on these Rule 30(b)(6) topics on the eve of the witness's already-scheduled individual deposition, but then declined to allow Bayer to question the witness on the Rule 30(b)(6) topics at the close of the witness's individual deposition, claiming that the amount of time allocated for the deposition had expired.

April 14, 2006

/s/ Richard D. Raskin

Richard D. Raskin

Michael Doss

SIDLEY AUSTIN LLP

1 S. Dearborn Street

Chicago, Illinois 60603

312-853-7000 (tel.)

312-853-7036 (facsimile)

Attorneys for Defendant Bayer Corporation

CERTIFICATE OF SERVICE

I hereby certify that on April 14, 2006, I caused a true and correct copy of Defendants Bayer Corporation's First Motion to Compel The State of Montana To Produce A Rule 30(b)(6) Witness, together with accompanying exhibits, to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2 in MDL No. 1456.

/s/ Michael Doss

EXHIBIT A



**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESale PRICE
LITIGATION

MDL No. 1456
CIVIL ACTION: 01-CV-12257-PBS

Judge Patti B. Saris
Chief Magistrate Judge Marianne B. Bowler

THIS DOCUMENT RELATES TO
STATE OF MONTANA V. ABBOTT
LABORATORIES, ET. AL.
CA NO. 02-12084-PBS

**DEFENDANT BAYER CORPORATION'S NOTICE OF RULE 30(B)(6) DEPOSITION
TO STATE OF MONTANA**

PLEASE TAKE NOTICE that pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure, Defendant Bayer Corporation ("Bayer"), by and through its counsel, will take the deposition upon oral examination of a representative or representatives designated by the State of Montana (hereinafter "Plaintiff") to testify on behalf of Plaintiff concerning all matters described herein, before a Notary Public or other person authorized to administer oaths at the offices of Gough, Shanahan, Johnson & Waterman, 33 S. Last Chance Gulch, P.O. Box 1715, Helena, MT, 59601, on February 23, 2006, at 9:30am. The deposition will be recorded by stenographic and/or sound and visual means and will continue from day to day until completion.

Pursuant to Rule 30(b)(6), Plaintiff shall designate in writing to the undersigned counsel for Bayer one or more officers, officials, employees, or other representative to testify on their behalf who are most knowledgeable about and will testify as to matters known or reasonably

available to Plaintiff in regard to the matters set forth below. Plaintiff is further requested to set forth the matter or matters on which each such designated person will testify.

All terms used in this Notice, whether or not capitalized, shall be defined as stated in Defendant Bayer Corporation's First Set of Interrogatories and Requests for Production to the State of Montana.¹

Unless otherwise specified, the relevant time period is the period from January 1997 to the present.

AREAS OF INQUIRY

Plaintiff is requested to designate one or more persons who consent to testify on its behalf concerning the following matters:

1. Plaintiff's use or consideration of Bayer ASP Information, including how or if such Bayer ASP Information has been used, relied upon, referenced, or considered in evaluating, revising, or setting payments to Providers under Plaintiff's Medicaid Program.
2. Communications between Plaintiff and the National Association of Medicaid Fraud Control Units ("NAMFCU") concerning the Bayer 2001 Settlement or concerning the Bayer 2003 Settlement (or any investigation or inquiry that preceded those Settlements), including internal analysis, memoranda, reports, and reviews related to communications with NAMFCU.

¹ Such defined terms include the Bayer 2001 Settlement, the Bayer 2003 Settlement, and Bayer ASP Information.

Dated: January 31, 2006

By: /s/ Michael Doss

Richard D. Raskin

Michael Doss

SIDLEY AUSTIN LLP

One S. Dearborn Street

Chicago, IL 60603

Tele: (312) 853-7000

Fax: (312) 853-7036

Counsel for Defendant Bayer Corporation

CERTIFICATE OF SERVICE

I, Michael Doss, hereby certify that on January 31, 2006, I have caused a true and accurate copy of the foregoing DEFENDANT BAYER CORPORATION'S NOTICE OF RULE 30(B)(6) DEPOSITION TO STATE OF MONTANA to be served on all counsel of record by electronic service, pursuant to Paragraph 11 of Case Management Order No. 2, by sending a copy to Lexis/Nexis for posting and notification to all parties.

Date: Chicago, Illinois
January 31, 2006

/s/ Michael Doss

Michael Doss

EXHIBIT B



NATIONAL ASSOCIATION OF MEDICAID FRAUD CONTROL UNITS
750 FIRST STREET NE SUITE 1100
WASHINGTON, DC 20002
(202) 328-8020
(202) 328-0884 FAX

BARBARA L. ZELNER
Counsel

PRESIDENT
ELLYN STERNFIELD
Assistant Attorney General
Director, MFCU
Oregon Attorney General's Office

VICE PRESIDENT
CHARLES W. GAMBRELL, JR.
Assistant Deputy Attorney General
Director, MFCU
South Carolina Attorney General's
Office

IMMEDIATE PAST PRESIDENT
L. TIMOTHY TERRY
Senior Deputy Attorney General
Director, MFCU
Nevada Attorney General's Office

January 29, 2001

Alaska Pharmacy Director
State Medicaid Agency
4501 Business Park Blvd.
Suite 24
Anchorage, Alaska 99503

Dear Medicaid Pharmacy Director:

The joint State and federal investigation of drug price misrepresentation by pharmaceutical manufacturers has resulted in the first concluded settlement with a manufacturer, Bayer, Inc. Under the terms of this settlement, Bayer will repay a total of \$14 million to cover excess Medicaid payments made for its products, and will enter into a Corporate Integrity Agreement with the Office of the Inspector General of the U. S. Department of Health and Human Services, to ensure the future accuracy and integrity of drug price communications.

Most importantly, from your perspective, the agreement reached requires Bayer to submit to all Medicaid Pharmacy Directors* whose states have entered into the settlement, along with First DataBank and HCFA OIG, quarterly certified statements identifying the actual average sale prices of its products, weighted to reflect the volume of sales at each price. Indeed, it is our

* The average sale price information will be sent to the same address as this letter. If you wish to designate another address, please notify your State MFCU of your desire to do so.

intention to make the communication of certified pricing data a mandatory component of any subsequent resolutions of our drug pricing investigation with pharmaceutical manufacturers. This unprecedented access to true market prices will provide you an extraordinary opportunity to compare providers' real acquisition costs with Medicaid reimbursement prices and, we believe, provide you the basis for determining where and how Medicaid prices should be adjusted.

Obviously, while this data has enormous potential value, its true benefits can only be achieved through the efforts of State pharmacy directors to make use of it. *We emphasize that each State will be obliged to determine how this data can be accommodated into its existing pricing formula. Unless and until states take such efforts, and provide First DataBank with specific instructions as to how the data is to be used, this pricing information will have no effect.* Consequently, we write to inform you at the earliest stage possible of the nature and import of the pricing data you will be receiving soon from Bayer and subsequently from other manufacturers.

The New Price Information You Will Receive

First, we wish to clearly communicate to you what the numbers you will be receiving represent. As set forth in the settlement, manufacturers will be submitting to each state:

"...the average of all final sale prices charged by [the manufacturer] for the drug or biological product in the United States to all purchasers, excluding those sales exempt from inclusion in the calculation of "Best Price" for Medicaid Rebate Program purposes, pursuant to 42 USC § 1396r-8, and direct sales to hospitals....net of all the following: volume discounts; prompt pay discounts; cash discounts; chargebacks; short-dated product discounts; free goods; rebates and all other price concessions provided by [the manufacturer]...that result in a reduction of the ultimate cost to the purchaser."

Thus, "average sale price" should be understood to mean exactly what it says; it is neither an Average Wholesale Price, nor a Wholesale Acquisition Cost, but the *average* of all prices charged to the overwhelming majority of customers. This average sale price will, moreover, be weighted to reflect the volume of sales at each price, *i.e.*, ten sales at \$1.00 and one sale at \$0.50 will produce, not a flat average of \$0.75, but a weighted average sales price of \$0.95.

Additionally, under the terms of the settlement, Bayer will refrain from submitting AWP information for purposes of setting Medicaid reimbursement for the following drugs:

- Koate-HP Antihemophilic Factor (Human)
- Kogenate Antihemophilic Factor (Recombinant)
- Konyne-80 Factor IX Complex (Human)
- Gamimmune N, 5% Immune Globulin Intravenous (Human, 5%),
- Gamimmune N, 10% Immune Globulin Intravenous (Human, 10%),
- Thrombate III Antithrombin III (Human).

First DataBank will consequently ascertain and communicate a Medicaid AWP for these products independently of any information from Bayer. Bayer will continue to submit AWP for other drugs it manufactures, but we reemphasize that the average sale price information Bayer will provide to State Medicaid programs will encompass *all* of its products.

Use of the Average Sale Price Data

A drug's average sale price will consequently afford you a reliable standard for determining what the true market price of a drug is, at least on an average basis. How this information may ultimately be used and what relationship this market price will or should bear to final reimbursement prices are, of course, questions properly left to you and other Program personnel. The Medicaid Fraud Control Units involved in this investigation have pursued the limited goals of halting the communication of false information, and ensuring that Medicaid Program staff have reliable information on which to make decisions. Once those goals have been achieved, the determination as to what levels of reimbursement ought to be, relative to a drug's average sale price, is appropriately left for consideration by Pharmacy Directors, Medicaid Program Directors and other policy makers. *Again, absent your direction to First DataBank, or any subsequent price reporting agency, as to how your state wishes use average sale price information, this data will have no impact on Medicaid prices and you will continue to be susceptible to any price misrepresentations by manufacturers.*

The Impact on Bayer

Another matter we wish to address concerns Bayer, the initial manufacturer to reach a resolution of its AWP liability. As such, Bayer will be, at least for a time, the only manufacturer to provide you with certified average sale price information, and how that information is used may have a profound effect on our continuing investigation. Our inquiry has indicated that Medicaid providers who bill for pharmaceuticals maximize their reimbursement by migrating to drugs with a high "spread" between AWP and purchase price, and away from lower spread drugs. Consequently, the existing market exhibits the perverse effect of "punishing" the truthful reporter of price data, whose lower reimbursement cannot compete with the larger spread generated by dishonest competitors. Were the Bayer price data to be used to cause this same result – lowering the market appeal of its products relative to its competitors – the effect would be doubly perverse: truthful price reporting by the first company to reach a settlement with the Medicaid Fraud Control Units would operate only to its economic disadvantage. It could hardly be expected that, if this were the outcome, any other manufacturer would consider either providing accurate price data or entering into a settlement with the government.

Of course, we stress, this is not to suggest that the Bayer information not be used. On the contrary, we would *urge* that it be used, effectively and productively, but in a way that provides no competitive advantage to other manufacturers less cooperative and less truthful than Bayer is. Again, the means by which this might be accomplished, e.g., by using Bayer data as a basis for setting State maximum prices, are subjects better left to your discretion.

As we indicated previously, we expect that our continuing investigation will result in more such negotiated resolutions with other pharmaceutical manufacturers in the future. It is our

intention that the provision of accurate information, enforced by the prospect of severe penalties for false submissions in every state, will enable Program reimbursements to be determined far more fairly and rationally than they are at present. We hope that you perceive the potential of this certified pricing data with an equally positive perspective.

Thank you for your continued cooperation and consideration in this matter.

Very truly yours,

For the NAMFCU Drug Pricing Team:

Patrick E. Lupinetti Special Assistant Attorney
General, New York MFCU
Kerry O'Brien, Director Maine MFCU
Thomas F. Staffa, Assistant Deputy Attorney
General, New York MFCU
L. Timothy Terry, Director Nevada MFCU,
David Waterbury, Director Washington MFCU

cc: State MFCU Directors

EXHIBIT C



1 Donald A. Lattin
2 Nevada Bar # 693
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8 Richard D. Raskin
9 SIDLEY AUSTIN LLP
10 One South Dearborn Street
11 Chicago, Illinois 60603
12 (312) 853-7000 (telephone)
13 (312) 853-7036 (fax)

14 Attorneys for Defendant Bayer Corporation

15
16
17 **IN THE SECOND JUDICIAL DISTRICT COURT OF THE STATE OF NEVADA**
18 **IN AND FOR THE COUNTY OF WASHOE**

19 STATE OF NEVADA,

20 Plaintiff,

21 v.

22 BAYER CORPORATION, and DOES 1 through
23 100,

24 Defendants.

Case No. CV 02-00260

Dept. No. 8

25 **DEFENDANT BAYER CORP.'S NOTICE**
26 **OF RULE 30(B)(6) DEPOSITION TO**
STATE OF NEVADA

27 **DEFENDANT BAYER CORPORATION'S NOTICE OF RULE 30(B)(6)**
28 **DEPOSITION TO STATE OF NEVADA**

29 PLEASE TAKE NOTICE that pursuant to Rule 30(b)(6) of the Nevada Rules of Civil
30 Procedure, Defendant Bayer Corporation ("Bayer"), by and through its counsel, will take the
31 deposition upon oral examination of a representative or representatives designated by the State of

1 Nevada (hereinafter "Plaintiff") to testify on behalf of Plaintiff concerning all matters described
 2 herein, before a Notary Public or other person authorized to administer oaths at the offices of
 3 Walther, Key, Maupin, Oats, Cox & Legoy, 4785 Caughlin Parkway, Reno, Nevada 89509, on
 4 February 23, 2006, at 9:30 a.m. The deposition will be recorded by stenographic and/or sound and
 5 visual means and will continue from day to day until completion.
 6

7 Pursuant to Rule 30(b)(6), Plaintiff shall designate in writing to the undersigned counsel for
 8 Bayer one or more officers, officials, employees, or other representative to testify on their behalf
 9 who are most knowledgeable about and will testify as to matters known or reasonably available to
 10 Plaintiff in regard to the matters set forth below. Plaintiff is further requested to set forth the matter
 11 or matters on which each such designated person will testify.
 12

13 All terms used in this Notice, whether or not capitalized, shall be defined as stated in
 14 Defendant Bayer Corporation's First Set of Interrogatories and Requests for Production to the State
 15 of Nevada.¹

16 Unless otherwise specified, the relevant time period is the period from January 1997 to the
 17 present.
 18

19 AREAS OF INQUIRY

20 Plaintiff is requested to designate one or more persons who consent to testify on its behalf
 21 concerning the following matters:

- 22 1. Plaintiff's use or consideration of Bayer ASP Information, including how or if such
 23 Bayer ASP Information has been used, relied upon, referenced, or considered in
 24

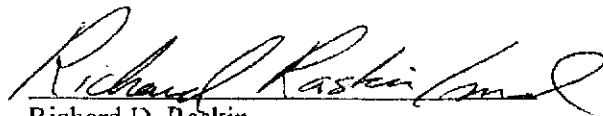
25
 26 ¹ Such defined terms include the Bayer 2001 Settlement and Bayer ASP Information.

1 evaluating, revising, or setting payments to Providers under Plaintiff's Medicaid
2 Program.

- 3 2. Communications between Plaintiff and the National Association of Medicaid Fraud
4 Control Units ("NAMFCU") concerning the Bayer 2001 Settlement (or any
5 investigation or inquiry that preceded this Bayer 2001 Settlement), including internal
6 analysis, memoranda, reports, and reviews related to communications with
7 NAMFCU.
8

9
10
11 Dated: January 31, 2006

By:



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Fax: (312) 853-7036

Counsel for Defendant Bayer Corporation

CERTIFICATE OF SERVICE

I, Michael Doss, an attorney with Sidley Austin LLP, hereby certify that I have caused a true and correct copy of the foregoing document to be served on the parties listed in the attached Service List as follows:

By Federal Express overnight delivery to:

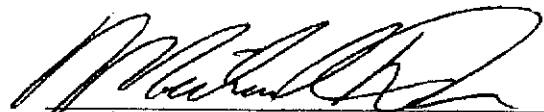
L. Timothy Terry
Chief Deputy Attorney General
198 N. Carson Street
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Telephone: (775) 684-1185
Counsel for Plaintiff

By facsimile and Federal Express overnight delivery to:

Steve W. Berman
Sean R. Matt
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Telephone: (206) 623-7292
Counsel for Plaintiff

By email transmission, with their consent, to all remaining counsel on the attached Service List.

DATED this 31st day of January, 2006



Michael Doss

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